

REMARKS/ARGUMENTS

Preliminarily, Applicants note that claims 1, and 24-26 have been currently amended. Amendments to claims 24-26 correct informalities. Claim 11 has been canceled as its limitations are present in currently amended claim 1.

As discussed below, Applicants respectfully request withdrawal of the restriction requirement as it is overly restrictive and improper under the PCT's Unity of Invention standard. The present application is a U.S. national stage application of a PCT application which was filed on February 3, 2004. Therefore, the Unity of Invention standard applies.

I) Election with Traverse

As a preliminary matter however, as required and to reserve the right to appeal the restriction requirement if made final, Applicants make the following elections with traverse:

Applicants elect Group III, claims 1-26, drawn to a system for treating or preventing restenosis providing interventional medical care to a patient.

Regarding the species restrictions:

Applicants elect coating on stent as a local delivery system.

Applicants elect implantable stent as the interventional medical device.

Applicants elect apoptosis DNA factor as the bioactive agent.

II) Identification of Claims Readable on Elected Species

Below is a listing of claims readable on the elected species:

Coating on stent as the local delivery system: Claims 1-26.

Implantable stent as the interventional medical device: Claims 1-26.

Apoptosis DNA factor as the bioactive agent: Claims 1, and 24-26.

III) Argument

Applicants respectfully traverse the present restriction requirement for the reasons below.

When making a lack of unity of invention requirement, the examiner must (1) list the different groups of claims and (2) explain why each group lacks unity with each other group (i.e., why there is no single general inventive concept) specifically describing the unique special technical feature in each group. MPEP § 1893(d).

Applicants submit that the Examiner has not met these requirements. The Examiner set forth ten groups to elect from: Group I-X. However, the Examiner has not specifically described the unique special technical feature in each group. The Examiner stated that the technical feature of Groups I and II is a system for treating or preventing atherosclerosis, stenosis, restenosis, smooth muscle cell proliferation, or other abnormal luminal cellular proliferation. (Restriction requirement dated 08/20/08, Page 3, ¶3). Although a technical feature common among the groups I and II, was set forth, the Examiner did not specifically describing the unique special technical feature in each group as required by MPEP § 1893(d). The Examiner did not address Groups III-X.

Also, the Examiner required Applicants to make very narrow species elections: a single and specific local delivery system, a single and specific interventional medical device, and a single and specific bioactive agent. In imposing such a narrow species election requirement, the Examiner was required also to describe the unique special technical feature in each species group not simply Group I and II and show why they are different. Thus, the burden of setting forth a proper restriction requirement under the PCT's unity of invention standard was not met.

When the Unity of Invention standard is appropriately applied, the Office should conclude that a single general inventive concept exists. Annex B of the Administrative Instructions Under the PCT (A158 in MPEP) illustrates that the present case is one of

the particular situations for which the method for determining unity of invention contained in Rule 13.2 and where unity of invention is present.

The method for determining unity of invention under Rule 13.2 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

- (i) in addition to an independent claim for a given product, an independent claim for a process specifically adapted for the manufacture of the said product, and an independent claim for a use of the said product, or
- (ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specifically designed for carrying out the said process, or
- (iii) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product and an independent claim for an apparatus or means specifically designed for carrying out the said process,... *Annex B, Administrative Instructions Under the PCT.*

In the present case, Groups I-X are related as systems and methods for treating or preventing a condition. The present systems and methods form a single general inventive concept just as the apparatus or means, product and process form a single general inventive concept in the quoted examples found in Annex B, Administrative Instructions Under the PCT.

In view of the foregoing, Applicants respectfully request the Examiner reconsider and withdraw the restriction requirement. It is also submitted that this application is now in good order for allowance and such allowance is respectfully solicited. Should the Examiner believe minor matters still remain that can be resolved in a telephone interview, the Examiner is urged to call Applicant's undersigned attorney.

The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 50-3207.

Respectfully submitted,

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